| | Application No. | Applicant(s) | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/827,846 | EDA ET AL. | |
| | Examiner | Art Unit | |
| | Gailene R. Gabel | 1641 | |
| The MAILING DATE of this communication at All claims being allowable, PROSECUTION ON THE MERITS herewith (or previously mailed), a Notice of Allowance (PTOL NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATEN of the Office or upon petition by the applicant. See 37 CFR 1 | S IS (OR REMAINS) CLOSED in -85) or other appropriate communication is such TRIGHTS. This application is such | this application. If not inclunication will be mailed in du | ided le course. THIS |
| 1. 🖂 This communication is responsive to Appellant's Brief to | <u>filed 6/22/04</u> . | | |
| 2. X The allowed claim(s) is/are 1-4, 6, 9, 10, 20, 22, and 23 | 3; now renumbered as claims 1-1 | 0, respectively. | |
| 3. \boxtimes The drawings filed on <u>19 December 2001</u> are accepted | l by the Examiner. | | |
| 4. Acknowledgment is made of a claim for foreign priorit a) □ All b) □ Some* c) □ None of the: 1. □ Certified copies of the priority documents here. 2. ☑ Certified copies of the priority documents here. 3. □ Copies of the certified copies of the priority International Bureau (PCT Rule 17.2(a)). * Certified copies not received: | ave been received. ave been received in Application | No. <u>09/129,744</u> . | ation from the |
| Applicant has THREE MONTHS FROM THE "MAILING DAT noted below. Failure to timely comply will result in ABANDO THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. | E" of this communication to file a NMENT of this application. | a reply complying with the re | equirements |
| 5. A SUBSTITUTE OATH OR DECLARATION must be su INFORMAL PATENT APPLICATION (PTO-152) which | bmitted. Note the attached EXAN gives reason(s) why the oath or o | MINER'S AMENDMENT or declaration is deficient. | NOTICE OF |
| 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") r (a) ☐ including changes required by the Notice of Draftsp 1) ☐ hereto or 2) ☐ to Paper No./Mail Date (b) ☐ including changes required by the attached Examin | erson's Patent Drawing Review (| | |
| Paper No./Mail Date Identifying indicia such as the application number (see 37 CF each sheet. Replacement sheet(s) should be labeled as such | R 1.84(c)) should be written on the | drawings in the front (not th | e back) of |
| 7. DEPOSIT OF and/or INFORMATION about the de attached Examiner's comment regarding REQUIREMEN | posit of BIOLOGICAL MATER | RIAL must be submitted. | Note the |
| Attachment(s) 1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-946) 3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SI Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit | B) 6. ☑ Interview Sum Paper No./M. 7. ☐ Examiner's Ar it 8. ☑ Examiner's St 9. ☐ Other | rmal Patent Application (PT nmary (PTO-413), ail Date <u>8/11/04</u> . mendment/Comment atement of Reasons for Alle | , |

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REASONS FOR ALLOWANCE

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- 1. The following is an examiner's statement of reasons for allowance: The prior art of record does not teach or fairly suggest an agglutination assay reagent comprising a binary population of microparticles having a mean diameter size of 30 nm to 600 nm and capable of causing light scattering a wavelengths between 300 and 1200 nm, and wherein the first population of microparticles have a greater mean diameter, greater refractive index, stronger light scattering properties, and have a binding partner with a higher reactivity for an analyte than the binding partner for the analyte coated upon the corresponding second population of microparticles. Lindmo et al., cited for teaching a reagent comprising a binary mixture of microparticles in flow cytometry, does not teach or suggest a mean diameter of 30 nm to 600 nm for the microparticles for each population of microparticles. Grange et al., cited for teaching an agglutination reagent comprising 300 nm mean diameter of microparticles does not teach or suggest binary populations of microparticles in the reagent for use in an agglutination assay.
- 2. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel Patent Examiner Art Unit 1641 August 11, 2004

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CHRISTOPHER L. CHIN PRIMARY EXAMINER GROUP 1800-1641

Christyn L. Chin